

Amendments to the Specification

At specification page 1, after the paragraph beginning with "[t]his is a nationalization," insert the following headings:

BACKGROUND OF THE INVENTION

1. Field of Invention

At specification page 1, replace the paragraph beginning with "[t]he present invention relates to" with the following replacement paragraph:

The present invention relates to haemodialysis equipment in general, and ~~it~~ more particularly relates to container bags for powdery saline compounds for the preparation of a liquid concentrate used in haemodialysis machines[[],]. ~~and it more particularly refers~~ The present invention also relates to the use of ~~it's~~ a manufacturing procedure ~~for that provides~~ a compartmented bag for haemodialysis machines[[],]. ~~it's main~~ A primary object ~~being directed of the invention is to obtaining~~ provide a bag assembly that avoids the use of inner solution suction tubing[[],]. Such inner solution suction tubing, which carries a tubular filter mounted at the end, ~~that~~ has been used in prior embodiments to preclude the dissolving powder from migrating out of the device before ~~it~~ the powder is dissolved.

At specification page 1, replace the paragraph beginning with "[t]he invention solves" with the following replacement paragraph:

The invention solves these problems by providing a bicompartiment bag comprising the characteristics of claim 1 having an assembly of two strong flexible outer sheets with an access bushing affixed through one of the sheets. The invention also provides a process of manufacturing a the bicompartiment bag according to the invention comprising the process steps of claim 12. Specific embodiments are the subject of the subclaims.

At specification page 1, replace the paragraph beginning with "[i]n order to solve the problems," with the following replacement paragraph:

In order to solve the the aforementioned problems, the invention replaces the the abovementioned above-described prior art filter to prevent the undissolved powder from leaking with a microperforated sheet to prevent the undissolved powder from leaking. The microperforated sheet acting acts as a partition between the a first zone or chamber where the undissolved powder is stored and a second chamber through which the solution exiting exits. through the second chamber, whereas the The prior art entrance filter is replaced in the present invention by a cross-shaped valve-like device built into the stopper.

At specification page 2, replace the paragraph beginning with "[t]he advantages of the present invention" with the following replacement paragraph:

The advantages of the present invention are as follows:

a) Lower cost due to the elimination of the ~~referred above-described~~ filters and ~~the abovementioned~~ exit tube for the solution mixed in the bag,

b) Insertion of the separating sheet defining two chambers;

c) Addition of ~~the a~~ draining sheet in the exit chamber, which adopts a tie-like configuration, and which, due to its irregular surface, ~~allows for~~ enables the liquid to be drained between the two plastic sheets defining the chamber, such that by flowing through the microperforated zone ~~it~~ the liquid easily drains toward the outlet port and

d) Assembling the container in a single procedure at the production plant, with the consequent labour reduction resulting from the lesser number of operations to conduct.

At specification page 2, replace the paragraph beginning with "[i]n summary," with the following replacement paragraph:

In summary, the invention further provides a new, extremely simple constructive procedure, to make it suitable to optimally ~~reach~~ attain its aim objects, including providing a means to divide the container into two separate chambers, in one of which

the powdered product to be converted into a concentrate used in haemodialysis is to be stored.

At specification page 2, line 27, replace the heading with the following replacement heading:

~~PREVIOUS ART~~ 2. Description of the Prior Art

At specification page 2, replace the paragraph beginning with "[b]ags prepared to contain" with the following replacement paragraph:

Bags prepared to contain the salt used to achieve the saline concentrate to be used in haemodialysis machines, consisting, e.g., of sodium bicarbonate (NaHCO_3) (NaHCO_3) , for dialysis carried out with such bicarbonate, are known in the previous art.

At specification page 4, after the paragraph beginning with "[i]t is worth mentioning," insert the following heading:

SUMMARY OF THE INVENTION

At specification pages 4-5, replace the paragraph beginning with "[t]his embodiment" with the following replacement paragraph:

This embodiment, apart from the remarkable simplification of the bag structure, which makes its construction considerably

simpler, divides the interior of the bag into two chambers, one of which is filled with the powdered bicarbonate through which the diluting water must circulate; it succeeds in eliminating the filter with its tubing, which is replaced by a simple membrane which has a screen configuration at the required position and which may have the contour of a stripe. The membrane may be produced by microperforation, but it may also be a separate part that is joined to the separation sheet. The construction ~~allows to verify~~ provides for verification of the water-tightness of each unit prior to its filling with the powdered saline material, with the additional advantage that it favours the operation, thus achieving a good heat sealing of the contour due to the fact that the possibility of it being altered by the presence of the salt granules or particles which would later cause leaks is avoided, and it avoids the blockage problem for the suction of the dilution due to the drop caused by the machine pump suction, which could bind or attach the laminar layers comprising the solution suction chamber together.

At specification page 2, line 27, replace the heading with the following replacement heading and insert the following paragraph:

~~DISCLOSURE:~~ DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Further scope of applicability of the present invention will become apparent from the detailed description given

hereinafter. However, it should be understood that the detailed description and specific examples, while indicating preferred embodiments of the invention, are given by way of illustration only, since various changes and modifications within the spirit and scope of the invention will become apparent to those skilled in the art from this detailed description.

At specification page 8, replace the paragraph beginning with "[t]he bushing acts" with the following replacement paragraph:

The bushing 4 acts as an entry nozzle for the solvent water and an exit for the solution, which is seen in greater detail in Figure 3. ~~It~~ The bushing 4 is configured as an annular body [-4-] with a discoid base 11 of a larger diameter [-11-] wherein a radial tube 12 is positioned [-12-] ~~communicating its to~~ communicate a central axial space -13- with the outside through said discoid base 11. In said inner cylindrical cavity of the bushing there are two projecting threads -14- and a third one -15- adjacent to the outlet plane which is somewhat wider than the two previous ones. On the outlet, which has a larger diameter lip -16-, there is a small annular recess adjacent to thread -15-.

At specification page 8, replace the paragraph beginning with "[i]n this complementary member" with the following replacement paragraph:

In this complementary member 17 there is a cylindrical central tube -18-, which is inwardly stepwise in its mouth, defining the water inlet of the bag. ~~It~~ The cylindrical central tube 18 is surrounded by another higher cylinder -19- at the bottom of which there is at least one radial branch -20- towards the perimeter of the member 17, wherein a peripheral groove -21- is disposed. The outer contour of the member -17-, complementary of the bushing -4- provides a larger diameter portion -22- followed by a lesser diameter portion -23- to effect the water-tight coupling with the bushing -4-, in the inner cavity of which (i.e., in the central axial space -13-) it is affixed with the functional cooperation of the threads or ridges -24- of a larger gauge and those -25- of a lesser width, that are found around ~~it's~~ the contour of member 17.

At specification page 9, replace the paragraph beginning with "[t]he complementary piece," with the following replacement paragraph:

The complementary piece (i.e., lid or stopper 17), which serves as a stopper once the bag has been filled with sodium bicarbonate, is provided with a valve -26- (see Figures 6 and 7) which seals the axial water inlet tube -18-.

At specification page 9, replace the paragraph beginning with "[i]ts unique structure" with the following replacement paragraph:

~~It's~~ The unique structure of valve 26 is shown in a greater scale in Figure 7. Therein it can be seen that ~~it~~ valve 26 consists of a thin sheet [-26-] wherein some lesser strength lines -27- are provided in a cross-shaped configuration and ending in grooves -28- penetrating to a depth in on the order of one half of the ~~valve~~ dise thickness of the valve -26-. These grooves 28 are disposed as a square engraved in the circular space of the tube -18- wherein the lines of a lesser strength come to an end.

At specification page 9, replace the paragraph beginning with "[f]igure 8 provides" with the following replacement paragraph:

Figure 8 provides a side view of the bicompartiment bag, after it has been assembled and the filling operation of chamber -A- with the sodium bicarbonate salt C to be diluted has been completed, thus being ready to be stoppered by the second complementary member -17-, now acting as a stopper. Adjacent to ~~it~~ chamber A there is chamber -B- through which the dilution to be effected is withdrawn once ~~it~~ the bag is mounted on the machine.

At specification page 9, replace the paragraph beginning with "[a]ll of the details" with the following replacement paragraph:

All of the details comprised ~~in~~ by the invention and the way to assemble the same are clearly established in the process. Once the bag is finished, it is already operative to be subjected to water-tightness and strength tests, which are carried out under at least twice the ~~work~~ operating pressure. This testing allows for the verification of the quality standards of each bag and for disposing of ~~such~~ those units not meeting the required specifications without undue financial damage. Only then are ~~they~~ the bags sterilized and filled with the required amount of the product to be dissolved, which in ~~this case~~ the example described herein is ~~Na~~ sodium bicarbonate. The bags are then present in the configuration shown in Figure 8, before the moment when the corresponding lids -17- are snapped on, for which purpose the threads and recesses machined in both pieces cooperatively work. Inside the outlet of the hemodialysis machine there is a conical punch that opens the valve -26 - by tearing the lesser strength lines -27- and separating them by virtue of their flexibility, for which the grooves -28-, acting as hinges, allow for the motion of the resulting triangular fragments, thus allowing for the circulation of the solvent water. ~~This valve~~ Valve 26 has prevented the salt from leaking, since ~~it~~ the valve is originally intact in

its closed position, and allows for the inspection and for any manipulation of the units without any problem whatsoever.

At specification page 11, after the last line, insert the following paragraph:

The invention being thus described, it will be apparent that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the invention, and all such modifications as would be recognized by one skilled in the art are intended to be included within the scope of the following claims.

At specification page 12 (i.e., the first claims page), replace the heading with the following replacement heading:

CLAIMS WHAT IS CLAIMED IS: